EJAX® GRIPE WATER

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM:
EJAX® GRIPE WATER (Solution)

COMPOSITION:
Each 5 ml contains:

Sodium bicarbonate	50 mg
Alcohol (100 %)	3,84 % *v/v*
Preservative:	
Sodium methyl hydroxybenzoate	0,1 % *m/v*
Excipients: aniseed oil, dill seed oil and purified water	
Contains sugar: Sucrose	1,17 g / 5 ml
Contains TARTRAZINE.	

PHARMACOLOGICAL CLASSIFICATION:
A 11.10 Medicines acting on gastro-intestinal tract – Others.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Sodium bicarbonate is an antacid that neutralises acid secretions in the gastrointestinal tract.
Pharmacokinetic properties
Sodium bicarbonate neutralises gastric acid secretions with the production of carbon dioxide. Bicarbonate not involved in neutralising gastric acid is absorbed and in the absence of a deficit of bicarbonate in the plasma, the bicarbonate ions are then excreted in the urine rendering it alkaline, and there is an accompanying diuresis.

INDICATIONS:
EJAX® GRIPE WATER relieves acidity in infants and children.

CONTRAINDICATIONS:
EJAX® GRIPE WATER is contraindicated in:
- patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria
- patients who are hypersensitive to sodium bicarbonate or to any of the ingredients of EJAX® GRIPE WATER (see COMPOSITION).

WARNINGS AND SPECIAL PRECAUTIONS:
EJAX® GRIPE WATER should be given extremely cautiously to patients with heart failure, oedema, renal impairment, hypertension or aldosteronism.
Special care must be taken when administering EJAX® GRIPE WATER with other medicines, and in particular with salicylates, tetracyclines, barbiturates and lithium. (Refer to Interactions).
EJAX® GRIPE WATER contains a high percentage of alcohol.
EJAX® GRIPE WATER contains FD and C Yellow No 5 (Tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of tartrazine sensitivity in the general population is currently thought to be low, it is frequently seen in patients who also have aspirin sensitivity.
EJAX® GRIPE WATER contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:
Bicarbonate may reduce or increase the rate and/or extent of absorption of a number of medicines due to raising intra-gastric pH. Alkalinisation of the urine leads to increased renal clearance of acidic medicines such as salicylates, tetracyclines and barbiturates. Conversely it may prolong the half-life of certain medicines and result in toxicity.
Sodium bicarbonate enhances the excretion of lithium. (Refer to Warnings and Special Precautions).

PREGNANCY AND LACTATION:
Not applicable. EJAX® GRIPE WATER is not intended for administration to women of child-bearing age.

DOSAGE AND DIRECTIONS FOR USE:
Give 3 to 4 times a day between meals and at bedtime as required.

New-born infants:	A half medicine measure (2,5 ml)
1 – 6 months:	One medicine measure (5 ml)
Over 6 months – 2 years:	Two medicine measures (10 ml)
Over 2 years:	Two to three medicine measures (10 – 15 ml)

SIDE EFFECTS:
The following side effects may occur:
Gastrointestinal disorders
Frequency unknown: Stomach cramps, belching, flatulence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Excessive use of bicarbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop, especially in hypocalcaemic patients. Treatment of metabolic alkalosis associated with bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride and potassium ions may be of particular importance.
Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality (hypernatraemia). Symptoms of hypernatraemia include thirst, reduced salivation, lachrymation, fever, sweating, tachycardia, hypertension or hypotension, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, somnolence, confusion, convulsions, coma, respiratory failure, and death. Treatment for mild sodium excess includes drinking water and restricting sodium intake.

IDENTIFICATION:
Yellow liquid

PRESENTATION:
100 ml clear, round PVC bottle with a white cap, contained in an outer carton.

STORAGE INSTRUCTIONS:
Store at or below 25 °C.
KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
M/11.10/537

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION:
Avid Brands (Pty) Ltd
Suite 9, Hillcrest Office Park
2 Old Main Road
Hillcrest, 3610

DATE OF PUBLICATION OF THE PACKAGE INSERT:
17 February 2017

EJAX® GRIPE WATER

SKEDULERINGSTATUS: S0

EIENDOMSNAAM EN DOSEERVORM:
EJAX® GRIPE WATER (Oplossing)

SAMESTELLING:
Elke 5 ml bevat:

Natriumbikarbonaat	50 mg
Alkohol (100 %)	3,84 % v/v
Bewaarmiddel:	
Natriummetielhidroksibensoaat	0,1 % m/v
Hulpstowwe: anysolie, dille-saadolie en gesuiwerde water	
Bevat suiker: Sukrose	1,17 g/5 ml

Bevat TARTRASIEN.

FARMAKOLOGIESE KLASSIFIKASIE:
A.11.10 Medisyne wat op die gastro-intestinale weg werk - ander.

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Natriumbikarbonaat is 'n teensuurmiddel wat suurafskeidings in die spysverteringskanaal neutraliseer.
Farmakokinetiese eienskappe
Natriumbikarbonaat neutraliseer maagsuurafskeidings met die produksie van koolstofdioksied. Bikarbonaat wat nie by die neutralisering van maagsuur betrokke is nie, word geabsorbeer en in die afwesigheid van 'n tekort aan bikarbonaat in die plasma, word die bikarbonaatione in die urien uitgeskei, wat dit alkalies maak, en daar is 'n gepaardgaande diurese.

INDIKASIES:
EJAX® GRIPE WATER verlig suur in babas en kinders**.**

KONTRA-INDIKASIES:
EJAX® GRIPE WATER is teenaangedui vir:
- pasiënte met metaboliese of respiratoriese alkalose, hipokalsemie of hipochloorhidrie
- pasiënte wat oorgevoelig is vir natriumbikarbonaat of vir enige van die bestanddele van EJAX® GRIPE WATER (kyk SAMESTELLING).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
EJAX® GRIPE WATER moet uiters versigtig gegee word aan pasiënte met hartversaking, edeem, swak nierfunksie, hipertensie of aldosteronisme.
Wees besonder versigtig wanneer EJAX® GRIPE WATER saam met ander medisyne gegee word, en veral saam met salisilate, tetrasikliene, barbiturate en litium (lees die Interaksies).
EJAX® GRIPE WATER bevat 'n hoë persentasie alkohol.
EJAX® GRIPE WATER bevat FD&C Yellow No. 5 (tartrasien) wat allergiese reaksies (waaronder brongiale asma) in sekere vatbare persone kan veroorsaak. Hoewel tans gereken word dat die totale insidensie van sensitiwiteit vir tartrasien in die algemene bevolking laag is, word dit dikwels waargeneem in pasiënte wat sensitief vir aspirien is.
EJAX® GRIPE WATER bevat sukrose wat 'n effek op die glisemiese beheer van pasiënte met diabetes mellitus kan hê.

INTERAKSIES:
Bikarbonaat kan as gevolg van die verhoging van die pH in die maag die tempo en/of mate van opname van 'n aantal middels verlaag of verhoog. Alkalinisering van die urien lei tot vinniger opruiming van suur medisyne soos salisilate, tetrasikliene en barbiturate deur die niere. Omgekeerd kan dit die halfleeftyd van sekere middels verleng en toksisiteit tot gevolg hê.
Natriumbikarbonaat verhoog die uitskeiding van litium (lees Waarskuwings en spesiale voorsorgmaatreëls).

SWANGERSKAP EN BORSVOEDING:
Nie van toepassing nie. EJAX® GRIPE WATER is nie bedoel vir toediening aan vroue in die vrugbare ouderdom nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Gee 3 tot 4 keer per dag tussen maaltye en teen slaaptyd soos nodig.

Pasgebore babas:	'n Halwe medisynemaat (2,5 ml)
1 - 6 maande:	Een medisynemaat (5 ml)
Ouer as 6 maande tot 2 jaar:	Twee medisynemate (10 ml)
Ouer as 2 jaar:	Twee tot drie medisynemate (10 - 15 ml)

NEWE-EFFEKTE:
Die volgende newe-effekte kan voorkom:
Gastro-intestinale versteurings
Frekwensie onbekend: maagkrampe, winde opbreek, winderigheid.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:
Oormatige gebruik van bikarbonaat kan tot hipokalemie en metaboliese alkalose lei , veral in pasiënte met swak nierfunksie. Simptome is onder meer buierigheid, moegheid, stadige asemhaling, spierswakheid en onreëlmatige hartklop. Spierhipertonisiteit, -trekkings en tetanie kan ontwikkel, veral in hipokalemiese pasiënte. Behandeling van metaboliese alkalose vanweë bikarbonaatoordosis is simptomaties en ondersteunend en behels hoofsaaklik die regstelling van vloeistof- en elektrolietbalans. Die vervanging van kalsium-, chloried- en kaliumione kan van besondere belang wees.
Oormatige dosisse van natriumsoute kan ook lei tot natriumoorbelading en hiperosmolaliteit (hipernatremie). Simptome van hipernatremie is onder meer dors, minder speekselafskeiding, tranerigheid, koors, sweet, tagikardie, hoë of lae bloeddruk, hoofpyn, duiseligheid, rusteloosheid, prikkelbaarheid, swakheid, spierkrampe en -styfheid, slaperigheid, verwardheid, stuiptrekkings, koma, asemhalingsversaking en dood. Behandeling van 'n klein oormaat natrium sluit in die drink van water en die beperking van die inname van natrium.

IDENTIFIKASIE:
Geel vloeistof

AANBIEDING:
100 ml deursigtige, ronde PVC-bottel met 'n wit prop in 'n buitekarton.

BEWARINGSINSTRUKSIES:
Bêre by of onder 25 °C.
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
M/11.10/537

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Avid Brands (Edms.) Bpk
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17 Februarie 2017